General

Guideline Title

Obinutuzumab in combination with chlorambucil for untreated chronic lymphocytic leukaemia.

Bibliographic Source(s)

National Institute for Health and Care Excellence (NICE). Obinutuzumab in combination with chlorambucil for untreated chronic lymphocytic leukaemia. London (UK): National Institute for Health and Care Excellence (NICE); 2015 Jun. 52 p. (Technology appraisal guidance; no. 343).

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

Obinutuzumab, in combination with chlorambucil, is recommended as an option for adults with untreated chronic lymphocytic leukaemia who have comorbidities that make full-dose fludarabine-based therapy unsuitable for them, only if:

- Bendamustine-based therapy is not suitable and
- The company provides obinutuzumab with the discount agreed in the patient access scheme

People whose treatment with obinutuzumab is not recommended in this National Institute for Health and Care Excellence (NICE) guidance, but was started within the National Health Service (NHS) before this guidance was published, should be able to continue treatment until they and their NHS clinician consider it appropriate to stop.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Chronic lymphocytic leukaemia

Guideline Category

Assessment of Therapeutic Effectiveness

Treatment

Clinical Specialty

Hematology

Internal Medicine

Oncology

Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To evaluate the clinical effectiveness and cost-effectiveness of obinutuzumab in combination with chlorambucil for untreated chronic lymphocytic leukaemia

Target Population

Adult patients (≥18 years) with untreated chronic lymphocytic leukaemia for whom full-dose fludarabine-based therapy is not appropriate

Interventions and Practices Considered

Obinutuzumab in combination with chlorambucil

Major Outcomes Considered

- Clinical effectiveness
  - Progression-free survival
  - Overall survival
  - Response rates
  - Adverse effects of treatment
  - Health-related quality-of-life (HRQL)
- Cost-effectiveness

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Care Excellence (NICE) commissioned an independent academic centre to perform an assessment of the manufacturer's submission on the technology considered in this appraisal and prepare an Evidence Review Group (ERG) report. The ERG report for this technology appraisal was prepared by Peninsula Technology Assessment group (PenTAG) (see the "Availability of Companion Documents" field).

Clinical Effectiveness

Critique of the Methods of Review(s)

Searches

The manufacturer provided detailed information on the search strategy. The database search strategies (as included in the manufacturer submission) are reproduced in Appendix 1 of the ERG report. In summary, searches were carried out in the following databases:

- MEDLINE (http://www.medline.com)
- EMBASE (http://www.elsevier.com/solutions/embase)
- PubMed (www.ncbi.nlm.nih.gov)
- The Cochrane Library

The Web sites of the American Society of Clinical Oncology (ASCO), the American Society of Haematology (ASH) and the European Haematology Association (EHA) were also searched for conference proceedings.

The searches were carried out in April 2014. The database searches combine free-text and Medical Subject Headings (MeSH) terms for "chronic lymphocytic leukaemia" and "Obinutuzumab". A variety of synonyms are used to ensure an appropriate balance of sensitivity and specificity. A suitable clinical trials filter is applied to the MEDLINE and EMBASE searches. All searches are date limited from 1992 to April 2014. The choice of databases is appropriate for the topic and the translation of search terms and syntax for each database is accurate.

Statement of the Inclusion/Exclusion Criteria Used in the Study Selection and Comment on Whether They Were Appropriate

Table. Eligibility Criteria Used in Search Strategy

Inclusion Criteria	Population: Adult patients (≥18 years) Outcomes: • Efficacy • Safety/Tolerability Study Design: Prospective randomised controlled trials (RCTs)
Exclusion Criteria	Study Design: • Observational studies • Single case studies Language Restrictions: Non-English publications were excluded. However, English abstracts of foreign language publications were included.

See Section 4 .4 of the ERG report for the search strategy for the mixed treatment comparison search performed by the manufacturer.

Cost-effectiveness

Manufacturer's Review of Cost-effectiveness Evidence

Search Strategy

The manufacturer provided detailed information on the search strategy. In summary, searches were carried out in the following bibliographic databases:

- EMBASE (ProQuest)
- EMBASE Alert (ProQuest)
- MEDLINE (ProQuest)
- National Health Service Economic Evaluation Database (NHS EED) (Centre for Reviews and Dissemination)
- EconLit (searched via the American Economic Association Web site)

The searches were run in May 2014. They combine free-text terms for "chronic lymphocytic leukemia" (American English spelling only) and free-text and MeSH terms for methods of cost-effectiveness analysis. The results are date limited from 1992 to May 2014.

ERG Comment on Search Strategy

The search strategy uses a variety of synonyms to ensure an appropriate balance of sensitivity and specificity. The lack of the UK English spelling for "leukemia" is a weakness. However, the searches were re-run by ERG's information specialist with the UK English spelling and no additional studies were retrieved, i.e., the number of hits when searching with and without the UK English spelling of "leukemia" is the same.

The term "lymphocytic" is spelt "lymphocitic" in the MEDLINE and EMBASE search strategies. The ERG raised this as a clarification question and the manufacturer responded by sending a revised appendix with a note that the spelling had been corrected. However, the spelling error remains in the revised appendix. The ERG re-ran the searches with the correct spelling and no additional studies were retrieved, i.e., the number of hits when searching with and without the correct spelling of "lymphocytic" is the same. As such, the error does not compromise the quality of the searches.

The translations of the ProQuest (i.e., MEDLINE and EMBASE) search strategies for NHS EED and EconLit are not equivalent to the ProQuest searches but they do contain the same concepts and are appropriate for the topic.

Inclusion and Exclusion Criteria Used in the Study Selection

Table. Inclusion and Exclusion Criteria for Systematic Review of Economic Evidence

Category	Include	Exclude
Population	People with first line CLL	Non-CLL; non-first line
Intervention	Obinutuzumab (GA101)	
Comparators	• Chlorambucil • Rituximab plus chlorambucil • Bendamustine • Rituximab plus bendamustine	
Outcomes	• Cost per quality-adjusted life-year gained • Cost per life-year gained	
Study Type	Economic evaluations: • Cost-effectiveness analyses • Cost-utility analyses • Cost minimisation analyses	RCTs, observational studies, budget impact assessments
Publication Type	Not specified	

Abbreviations: CLL, chronic lymphocytic leukaemia; RCTs, randomised controlled trials.

Number of Source Documents

Clinical Effectiveness

The PRISMA flow diagram (see Figure 2 in the ERG report [see the "Availability of Companion Documents" field]) records that 138 clinical effectiveness studies were retrieved by the database searches. There is a slight discrepancy between the PRISMA flow diagram and the database search strategies detailed in the appendix of the ERG report, which record 139 clinical effectiveness studies. An additional 13 records were identified by searching Web sites for conference abstracts. One study was included in the review.

See Section 4.4 in the ERG report for the results of the mixed treatment comparison literature search.

Cost-effectiveness

- Figure 20 of the ERG report shows the study flow diagram for the cost-effectiveness review. The searches conducted by the manufacturer identified 17 unique records, one of which met the inclusion criteria. The included study, published only as an abstract, evaluated obinutuzumab in combination with chlorambucil versus chlorambucil alone in people with previously untreated chronic lymphocytic leukaemia.
- The manufacturer submitted an economic model.

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus

Rating Scheme for the Strength of the Evidence

Not applicable

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Care Excellence (NICE) commissioned an independent academic centre to perform an assessment of the manufacturer's submission on the technology considered in this appraisal and prepare an Evidence Review Group (ERG) report. The ERG report for this technology appraisal was prepared by Peninsula Technology Assessment group (PenTAG) (see the "Availability of Companion Documents" field).

Clinical Effectiveness

Critique of Data Extraction

The submission explains the processes used in study selection and data extraction which is in line with the standard review process. The screening of the literature was performed by one reviewer and inclusion and exclusion criteria were verified by a second reviewer. Any disputes were resolved by a third party.

Quality Assessment

Only one randomised controlled trial (RCT) was included. Details of the manufacturer's critical appraisal of Study CLL11, alongside the ERG's critique, can be seen in Table 10 of the ERG report. The critical appraisal was performed using the Centre for Reviews and Dissemination (CRD) assessment criteria for risk of bias in RCTs.

Description and Critique of Statistical Approach

Statistical Analysis: Primary Endpoints

The statistical analysis of the primary data was performed from a clinical data cut-off on May 9th 2013.

Adjustments for multiplicity were done using a three-arm closed-test procedure. The first test was for any difference between the three treatment groups at an α=5%. If the null hypothesis of equal distributions for all three groups was rejected, pairwise tests for each of the three hypotheses (obinutuzumab plus chlorambucil versus chlorambucil alone, obinutuzumab plus chlorambucil versus rituximab plus chlorambucil, and rituximab plus chlorambucil versus chlorambucil alone) were enabled at the 5% alpha level without α-inflation. The closed test procedure was conducted separately for the investigator and independent review committee (IRC) assessed progression-free survival (PFS).

Treatment comparison was based on PFS using a two-sided stratified (by Binet Stage at baseline) log-rank test. A two-sided non-stratified log-rank test was done to confirm the primary analysis. Median PFS and the 95% confidence limits were estimated using Kaplan-Meier survival methodology.

Statistical Analysis: Secondary Endpoints

No adjustment for multiplicity was made for secondary endpoints: all were tested using a two-sided 5% alpha level. Time-to-event endpoints were analysed in a manner similar to the primary analysis. Best overall response rates and end of treatment response rates in the treatment groups were compared using a chi-square test with continuity correction. In addition, 95% confidence limits for the difference using the Anderson-Hauck approach were calculated. Response rates and 95% confidence limits according to Pearson-Clopper are provided for each treatment group. The proportion of responders and the corresponding 95% confidence interval (CI) for each of the response categories by treatment group is presented. The effect of prognostic factors is assessed in an exploratory analysis using logistic regression.

Refer to Section 4 in the ERG report for additional information on clinical effectiveness.

Cost-effectiveness

The quality assessment checklist suggested by NICE was applied even though the study found was only published in abstract form. Results from the included analysis, conducted by Roche, are summarised in Table 26 in the ERG report.

Model Structure

The submission includes a cohort Markov model, comprised of three states: progression free, progression and death. These are demonstrated in Figure 21 of the ERG report. The progression free health state is divided into two sub-states: on (initial) therapy and off therapy. Individuals in all arms remain on the treatment until they discontinue the therapy (due to adverse events), experience disease progression or die.

Individuals who have completed or discontinued treatment remain in the progression free health state until they progress or die. People in the progressed state remain in the state until they die and cannot return to the progression free health state. These patients are assumed to receive a course of chlorambucil.

The proportion of the cohort in each state is calculated as follows:

- The total proportion alive is set to the total proportion alive progression free plus the proportion alive in progress disease.
- The proportion in the progression free health state is set to equal the progression free survival curve.
- The proportion in the progression health state at each cycle is the difference between the proportion alive and the proportion that is progression free.

Cycles in the model last one week and a half-cycle correction was applied, except to the drug, administration and pharmacy costs.

Refer to sections 5 and 6 in the ERG report for more information on cost-effectiveness assessment.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Considerations

Technology appraisal recommendations are based on a review of clinical and economic evidence.

Technology Appraisal Process

The National Institute for Health and Care Excellence (NICE) invites 'consultee' and 'commentator' organisations to take part in the appraisal process. Consultee organisations include national groups representing patients and carers, the bodies representing health professionals, and the manufacturers of the technology under review. Consultees are invited to submit evidence during the appraisal and to comment on the appraisal documents.

Commentator organisations include manufacturers of the products with which the technology is being compared, the National Health Service (NHS) Quality Improvement Scotland and research groups working in the area. They can comment on the evidence and other documents but are not asked to submit evidence themselves.

NICE then commissions an independent academic centre to review published evidence on the technology and prepare an 'assessment report'. Consultees and commentators are invited to comment on the report. The assessment report and the comments on it are then drawn together in a document called the evaluation report.

An independent Appraisal Committee then considers the evaluation report. It holds a meeting where it hears direct, spoken evidence from nominated clinical experts, patients and carers. The Committee uses all the evidence to make its first recommendations, in a document called the 'appraisal consultation document' (ACD). NICE sends all the consultees and commentators a copy of this document and posts it on the NICE Web site. Further comments are invited from everyone taking part.

When the Committee meets again it considers any comments submitted on the ACD; then it prepares its final recommendations in a document called the 'final appraisal determination' (FAD). This is submitted to NICE for approval.

Consultees have a chance to appeal against the final recommendations in the FAD. If there are no appeals, the final recommendations become the basis of the guidance that NICE issues.

Who Is on the Appraisal Committee?

NICE technology appraisal recommendations are prepared by an independent committee. This includes health professionals working in the NHS and people who are familiar with the issues affecting patients and carers. Although the Appraisal Committee seeks the views of organisations representing health professionals, patients, carers, manufacturers and government, its advice is independent of any vested interests.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

Summary of Appraisal Committee's Key Conclusions

Availability and Nature of Evidence

The company presented a comparison of obinutuzumab plus chlorambucil therapy with chlorambucil monotherapy, chlorambucil plus rituximab therapy, bendamustine monotherapy, and bendamustine plus rituximab therapy.

European Organisation for Research and Treatment of Cancer Quality of Life (EORTC-QLQ) data were collected in CLL11, but were not mapped to the EuroQol (EQ-5D) or used in the model. Instead the company carried out a utility elicitation study to determine the utility values.

Uncertainties Around and Plausibility of Assumptions and Inputs in the Economic Model

Utility values were determined from a sample of the general population and not from people who had chronic lymphocytic leukaemia, and were not stratified by age. The Committee believed that the utility values used in the company's model were not reliable.

Several assumptions in the company's model were queried:

- The company used the incorrect utility value while on obinutuzumab treatment after the first cycle of obinutuzumab treatment.
- The utility value for progression-free survival off treatment in the company's model was based on the utility elicitation study.
- The company assumed a dose intensity of 100% for bendamustine and rituximab.
- The company used its large network meta-analysis to estimate a hazard ratio of 0.40 for the comparison with bendamustine monotherapy.
- The company used the estimated sample size from an ongoing trial (MaBLe) to calibrate the correlation between the number of people who had a complete response and the progression-free survival hazard ratio for treatment with bendamustine plus rituximab and treatment with rituximab plus chlorambucil.

The company submitted a patient access scheme and revised cost-effectiveness analyses that incorporated all of the Evidence Review Group's (ERG's) suggested amendments and the Committee's preferred amendments to some of the assumptions made by the company in the base-case analysis. The Committee concluded that the company's revisions to its economic model, including the patient access scheme, the ERG's suggested amendments and updated neutropenia costs, were appropriate and that the company's revised base-case cost-effectiveness estimates were the most appropriate for its decision-making.

Incorporation of Health-related Quality-of-Life Benefits and Utility Values. Have Any Potential Significant and Substantial Health-related Benefits Been Identified That Were Not Included in the Economic Model, and How Have They Been Considered?

EORTC-QLQ data were collected in CLL11 but were not mapped to the EQ-5D or used in the model. Utility values were determined from a sample of the general population and not from people who had chronic lymphocytic leukaemia and were not stratified by age. The Committee believed that the utility values used in the company's model were not reliable.

The Committee queried:

- The utility value used after the first cycle of obinutuzumab treatment in the company's model, which was based on progression-free survival off treatment. The Committee heard from the company that it had used the incorrect value. The ERG used a value based on progression-free survival on intravenous treatment.

The utility value for progression-free survival off treatment in the company's model was based on the utility elicitation study. The ERG highlighted that this utility value was higher than the utility value for the UK general population at a similar age to people with chronic lymphocytic leukaemia whose disease has not progressed and who are off treatment.

No additional benefits with obinutuzumab plus chlorambucil that were not already captured in the quality-adjusted life year (QALY) estimate in the modelling were identified.

Are There Specific Groups of People for Whom the Technology Is Particularly Cost Effective?

The Committee agreed that the population who cannot have fludarabine could be divided into people who can have bendamustine and those who cannot. It noted that for people who cannot have bendamustine, the most likely incremental cost-effectiveness ratios (ICERs) (including the patient access scheme) for obinutuzumab plus chlorambucil compared with both chlorambucil alone and with rituximab plus chlorambucil were all in the range considered cost effective (£20,000 to £30,000 per QALY gained).

What Are the Key Drivers of Cost-effectiveness?

The company identified the key drivers of the model as the long-term projection of progression-free survival, the post-progression death rate, the results of the large network meta-analysis and the utility values used.

Most Likely Cost-effectiveness Estimate (Given as an ICER)

For people who cannot have bendamustine, the Committee noted that the most likely ICERs (including the patient access scheme) for obinutuzumab plus chlorambucil compared with chlorambucil alone and with rituximab and chlorambucil were within the range considered cost effective (£20,000 to £30,000 per QALY gained).

For people who can have bendamustine, the Committee noted that the most likely ICERs (including the patient access scheme) for obinutuzumab plus chlorambucil compared with both bendamustine alone and with rituximab plus bendamustine were above the top end of the range that would normally be considered cost effective (£20,000 to £30,000 per QALY gained).

Method of Guideline Validation

External Peer Review

Description of Method of Guideline Validation

Consultee organisations from the following groups were invited to comment on the draft scope, assessment report and the appraisal consultation document (ACD) and were provided with the opportunity to appeal against the final appraisal determination.

- Manufacturer/sponsors
- Professional/specialist and patient/carer groups
- Commentator organisations (without the right of appeal)

In addition, individuals selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups were also invited to comment on the ACD.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

The Appraisal Committee considered evidence submitted by the manufacturer and a review of this submission by the Evidence Review Group (ERG). The main clinical effectiveness evidence came from one randomised controlled trial (RCT). For cost-effectiveness, the Appraisal Committee considered an economic model submitted by the manufacturer.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate use of obinutuzumab in combination with chlorambucil for untreated chronic lymphocytic leukaemia

Potential Harms

The summary of product characteristics lists the following common adverse reactions for obinutuzumab: urinary tract infection, nasopharyngitis, oral herpes, rhinitis, pharyngitis, squamous cell carcinoma of the skin, neutropenia, thrombocytopenia, anaemia, leukopenia, tumour lysis syndrome, hyperuricaemia, atrial fibrillation, hypertension, cough, diarrhoea, constipation, alopecia, arthralgia, back pain, musculoskeletal chest pain, pyrexia, decreased white blood cell count, decreased neutrophil count, increased weight and infusion-related reactions.

For full details of adverse reactions and contraindications, see the summary of product characteristics.

Contraindications

Contraindications

For full details of adverse reactions and contraindications, see the summary of product characteristics.

Qualifying Statements

Qualifying Statements

- This guidance represents the views of the National Institute for Health and Care Excellence (NICE) and was arrived at after careful

consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

- Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

Implementation of the Guideline

Description of Implementation Strategy

- Section 7(6) of the National Institute for Health and Care Excellence (NICE) (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 requires clinical commissioning groups, National Health Services (NHS) England and, with respect to their public health functions, local authorities to comply with the recommendations in this appraisal within 3 months of its date of publication.
- The Welsh Assembly Minister for Health and Social Services has issued directions to the NHS in Wales on implementing NICE technology appraisal guidance. When a NICE technology appraisal recommends the use of a drug or treatment, or other technology, the NHS in Wales must usually provide funding and resources for it within 3 months of the guidance being published.
- When NICE recommends a treatment 'as an option', the NHS must make sure it is available within the period set out in the paragraph above. This means that, if a patient has chronic lymphocytic leukaemia and the doctor responsible for their care thinks that obinutuzumab is the right treatment, it should be available for use, in line with NICE's recommendations.
- The Department of Health and Roche have agreed that obinutuzumab will be available to the NHS with a patient access scheme which makes it available with a discount. The size of the discount is commercial in confidence. It is the responsibility of the company to communicate details of the discount to the relevant NHS organisations. Any enquiries from NHS organisations about the patient access scheme should be directed to Roche Products, 01707 365736 or welwyn.rx_bdop@roche.com.
- NICE has developed tools to help organisations put this guidance into practice (listed below).
    - A costing statement explaining the resource impact of this guidance.

Implementation Tools

Mobile Device Resources

Patient Resources

Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

National Institute for Health and Care Excellence (NICE). Obinutuzumab in combination with chlorambucil for untreated chronic lymphocytic leukaemia. London (UK): National Institute for Health and Care Excellence (NICE); 2015 Jun. 52 p. (Technology appraisal guidance; no. 343).

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2015 Jun

Guideline Developer(s)

National Institute for Health and Care Excellence (NICE) - National Government Agency [Non-U.S.]

Source(s) of Funding

National Institute for Health and Care Excellence (NICE)

Guideline Committee

Appraisal Committee

Composition of Group That Authored the Guideline

Committee Members: Professor Andrew Stevens (*Chair of Appraisal Committee C*), Professor of Public Health, University of Birmingham; Professor Eugene Milne (*Vice Chair of Appraisal Committee C*), Director of Public Health for Newcastle upon Tyne; Professor Kathryn Abel, Director of Centre for Women's Mental Health, University of Manchester; Dr David Black, Medical Director, NHS South Yorkshire and Bassetlaw; David Chandler, Lay Member; Gail Coster, Advanced Practice Sonographer, Mid Yorkshire Hospitals NHS Trust; Professor Peter Crome, Honorary Professor, Department of Primary Care and Population Health, University College London; Professor Rachel A Elliott, Lord Trent Professor of Medicines and Health, University of Nottingham; Dr Greg Fell, Consultant in Public Health, Bradford Metropolitan Borough Council; Dr Alan Haycox, Reader in Health Economics, University of Liverpool Management School; Emily Lam, Lay Member; Dr Nigel Langford, Consultant in Clinical Pharmacology and Therapeutics and Acute Physician, Leicester Royal Infirmary; Dr Allyson Lipp, Principal Lecturer, University of South Wales; Dr Claire McKenna, Research Fellow in Health Economics, University of York; Dr Patrick McKiernan, Consultant Paediatrician, Birmingham Children's Hospital; Professor Gary McVeigh, Professor of Cardiovascular Medicine, Queen's University Belfast and Consultant Physician, Belfast City Hospital; Dr Andrea Manca, Health Economist and Senior Research Fellow, University of York; Dr Iain Miller, Founder and Chief Executive Officer, Health Strategies Group; Dr Paul Miller, Director, Payer Evidence, Astrazeneca UK Ltd; Professor Stephen O'Brien, Professor of Haematology, Newcastle University; Dr Anna O'Neill, Deputy Head of Nursing and Healthcare School/Senior Clinical University Teacher, University of Glasgow; Alan Rigby, Academic Reader, University of Hull; Professor Peter Selby,

Consultant Physician, Central Manchester University Hospitals NHS Foundation Trust; Professor Matt Stevenson, Technical Director, School of Health and Related Research, University of Sheffield; Dr Paul Tappenden, Reader in Health Economic Modelling, School of Health and Related Research, University of Sheffield; Professor Robert Walton, Clinical Professor of Primary Medical Care, Barts and The London School of Medicine and Dentistry; Dr Judith Wardle, Lay Member

Financial Disclosures/Conflicts of Interest

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Electronic copies: Available from the National Institute for Health and Care Excellence (NICE) Web site .

Availability of Companion Documents

The following are available:

- Obinutuzumab in combination with chlorambucil for untreated chronic lymphocytic leukaemia. Costing statement. London (UK): National Institute for Health and Care Excellence (NICE); 2015 Jun. 1 p. (Technology appraisal guidance; no. 343). Electronic copies: Available from the National Institute for Health and Care Excellence (NICE) Web site .
- Hoyle, M, Long, L, Huxley, N, Crathorne, L, Briscoe, S, Rudin, C. Obinutuzumab in combination with chlorambucil for previously untreated chronic lymphocytic leukaemia: a critique of the submission from Roche. Exeter (UK): Peninsula Technology Assessment Group (PenTAG), University of Exeter; 2014. 190 p. Electronic copies: Available from the NICE Web site .

Patient Resources

The following is available:

- Obinutuzumab in combination with chlorambucil for untreated chronic lymphocytic leukaemia. Information for the public. London (UK): National Institute for Health and Care Excellence (NICE); 2015 Jun. 3 p. (Technology appraisal guidance; no. 343). Electronic copies: Available from the National Institute for Health and Care Excellence (NICE) Web site . Also available for download in ePub or eBook formats from the NICE Web site . Also available in Welsh from the NICE Web site .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

This NGC summary was completed by ECRI Institute on July 15, 2015.

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